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4. TITLE AND SUBTITLE

The Accuracy and Precision of the CONMED ECMTM in the Porcine Model (sus scrofa – Yorkshire cross)

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5b. GRANT NUMBER

FWH20140100A

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5d. PROJECT NUMBER

FWH20140100A

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

FWH20140100A

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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10. SPONSOR/MONITOR'S ACRONYM(S)

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12. DISTRIBUTION/AVAILABILITY STATEMENT

Distribution A. Approved for public release; distribution unlimited.

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Background:The use of invasive monitoring is complicated by several factors. It is imperative for those wounded in battle that we explore potential technologies that can aid in the management of effective fluid resuscitation. Objectives:To explore the accuracy and precision of a FDA approved device, the CONMED by comparing it to the Edwards Vigilance II monitor pulmonary artery catheter under hypothermic and hemorrhagic conditions. Methods:8 anesthetized, instrumented and stabilized in exp. 1 (hemorrhage), induced Type III hemorrhagic conditions. CO values were collected from the PAC and the ECOM over a 3 hour period. Exp. 2 (hypothermia), swine were cooled to a temperature of 33oC and CO values recorded from both instruments. Results: The curves from the ECOM data were significantly different from the PAC data curves under both conditions, but more pronounced differences were found under hemorrhagic conditions. Conclusion: The ECOM does not appear to reliably reproduce CO values acquired from a traditional PAC under hemorrhagic conditions.

15. SUBJECT TERMS

pulmonary artery catheter, hemorrhage, battlefield medicine, resuscitation, shock, pig, animal model, hypothermic, hypothermia, hypovolemic, hypovolemia, CONMED ECOM, swine, sus scrofa

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Joseph K. Maddry
U	U	U	SAR		19b. TELEPHONE NUMBER *(Include area code)* 210-724-0654

59th Medical Wing
Institutional Animal Care and Use Committee (IACUC)
59 Clinical Research Division/SGVUS
1100 Wilford Hall Loop, Bldg 4430
Lackland AFB, TX 78236-5300

NOTICE OF ACTION REGARDING IACUC REVIEW

Date: 12 Dec 17

TO: Maj Joseph Maddry/59EMDS/SGO3D

Your **Final Report** was reviewed by the WHASC IACUC during the 14 Nov 17 meeting. The Committee's decision is provided below:

FWH20140100A (Research) "The Accuracy and Precision of the CONMED ECOMTM in the Porcine (Sus scrofa - Yorkshire cross) Model" **PI: Maj Joseph Maddry/59 EMDS/SGO3D**

Introduced at the 10 Oct 17 IACUC meeting: Due to conflicts of interest and early departures, the committee no longer met quorum requirements and therefore this item will be reviewed at the next convened meeting in November.

14 Nov 17: The committee voted that this item be approved as written. **FOLLOW-UP: CLOSED**

Name of Official	**Title/Office Symbol/Phone**
Elizabeth L. Prince	Office of Research Protocol Support /SGVUS/292-4210
Signature	Info Copy To

WHASC – Animal Final Report

Date: 26Sept2017

1. Protocol Number: FWH20140100A

2. Type of Research: Animal Research

3. Title: The Accuracy and Precision of the CONMED ECMTM in the Porcine Model (sus scrofa – Yorkshire cross)

4. Principal Investigator (PI):

Name	Rank	Date of IACUC Training	Branch of Service/ Corps	Staff Resident Fellow Civilian	Department / Office Symbol	Email (if other than WHASC Outlook)	Phone	Pager
Joseph Maddry	O-4	May 2014	USAF	Staff	59th EMDS/SG OED	Joseph.maddry@gmail.com	210-916-3693	

5. Purpose: The purpose of this study was to explore the accuracy and precision of a recently FDA approved device, the CONMED endotracheal cardiac output monitor (ECOM) ™ (device information in appendix) apparatus, by comparing it to the PAC in under hemorrhagic and hypothermic conditions.

6. Results: Using GraphPad Prism® to conduct non-linear fit analyses comparing the slopes of the curves for ECOM versus PAC, we found that the curves from the ECOM data were significantly different from the PAC data curves under both conditions, but more pronounced differences were found under hemorrhagic conditions. Future studies will compare the ECOM stroke volume variability data to the PAC catheter data. Stroke volume variation has been shown to be a reliable predictor of fluid responsiveness. These data may compare favorably.

7. How may your findings benefit the Air Force? If the CONMED ECOM proves to be accurate and precise, management of hypovolemic shock can be more precisely targeted to the need for fluid rather than vasoactive medications. Findings from studies may suggest improved short term and long-term survival for our injured service members with targeted care. Because the injured service member will very commonly have need for placement of an endotracheal tube for management of a patent airway. This device can potentially simplify acquisition of data while protecting the service member from the added potential complications associated with placement and maintenance of the PAC.

8. Number of Animals

Projected Enrollment of Animals at the Beginning of Study: 20

Actual Number of Animals Enrolled: 20

9. Status of Animals Entered into the Protocol: The animals were in good general health, and were euthanized at the end of the study per protocol.

10. Number of animals since last status report:

	Number enrolled since last report	Total enrollment to date
Number of animals entered into the Study	0	20

11. Status of Funds: There are no remaining funds. All funds were used accordingly.

12. Reason for Closure: Study is complete

13. Specific Problems: At the beginning of the study we identified a few issues with the ECOM monitor and tube. The tube was very positional and sensitive to movement of the animal. The ECOM monitor was sent back to the company for updates to the software that would allow the monitor to record information pertinent to the study.

14. Publications and Presentations:

Presentations:
"Comparison of an endotracheal cardiac output monitor to a pulmonary artery catheter" Tri Service Nursing Research Program; Elliot City, Maryland; April 25, 2017
"Comparison of an endotracheal cardiac output monitor to a pulmonary artery catheter" American Association of Nurse Anesthetists; Seattle, Washington; Sept 8 - 12, 2017

These Presentations and Publications have been cleared by 59 CRD and Public Affairs

Publications: None

15. Exceptional Achievements: None

16. Signature of Principal Investigator:

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